

Message

From: Dunlap, David [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=591EB15A268249DDA0C05A7451F765C3-DUNLAP, DAV]
Sent: 1/15/2021 2:41:53 AM
To: Hoverman, Taylor [hoverman.taylor@epa.gov]; Fischer, David [Fischer.David@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Jones, Lindsey (jones.lindsey@epa.gov) [jones.lindsey@epa.gov]
BCC: Dunlap, David [dunlap.david@epa.gov]
Subject: RE: PFAS Tox Values: OCSPP Review
Attachments: PFBS clearance draft 9.30.2020_Post InterAgency Review_INTERNAL DELIBERATIVE OCSPP Responses to IA Review_v2_01-14-21_Combined.docx

See below for my edits. I have also made conforming edits in the draft document (attached). See page 76 and 78. I move the peer review statement from the body of the document to a footnote (specifically footnotes 10 and 12).

Please review and provide your feedback.

Thanks

DDD

David D. Dunlap
O – 202.564.6620

From: Hoverman, Taylor <hoverman.taylor@epa.gov>
Sent: Thursday, January 14, 2021 7:42 PM
To: Fischer, David <Fischer.David@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>
Subject: RE: PFAS Tox Values: OCSPP Review

David's & Alex – Can you help me write a better response to this DOD comment, so we can send the response to comments back to OMB **tonight** asking for clearance by 10am tomorrow prior to elevating the issue? THANK YOU!


DOD
It is EPA's prerogative to address science policy issues, but to state on pages 76 and 78 that "The selection of UFs is a science policy judgement and therefore not the subject of outside peer review." is entirely inconsistent with the charge questions used in the two rounds of external peer review. It is also inconsistent with the scores of toxicological assessments whose interagency review we have engaged. Both times for PFBS, EPA asked the external peer reviewers to opine on the UFs and it is notable that each time the panel was in agreement with the UFDs applied. To say now that UFs are not subject to external peer review is disingenuous and also is precedent setting, we recommend this be deleted.

Response: Ex. 5 Deliberative Process (DP)

Ex. 5 Deliberative Process (DP)

Taylor Meredith
Senior Advisor to the Administrator

U.S. Environmental Protection Agency

 Ex. 6 Personal Privacy (PP)

O: 202-566-2705

From: D'Amico, Louis <DAmico.Louis@epa.gov>

Sent: Thursday, January 14, 2021 7:03 PM

To: Hoverman, Taylor <hoverman.taylor@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>

Cc: Dunlap, David <dunlap.david@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Stedeford, Todd <Stedeford.Todd@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Wheeler, Kevin <Wheeler.Kevin@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>

Subject: RE: PFAS Tox Values: OCSPP Review

Taylor,

Please see the assessment and response to comments attached to this email. The response to comment document covers comments from HHS and DOD that were included in the body of emails from OMB. There is one outstanding comment from DOD that remains to be addressed:

DOD

It is EPA's prerogative to address science policy issues, but to state on pages 76 and 78 that "The selection of UFs is a science policy judgement and therefore not the subject of outside peer review." is entirely inconsistent with the charge questions used in the two rounds of external peer review. It is also inconsistent with the scores of toxicological assessments whose interagency review we have engaged. Both times for PFBS, EPA asked the external peer reviewers to opine on the UFs and it is notable that each time the panel was in agreement with the UFDs applied. To say now that UFs are not subject to external peer review is disingenuous and also is precedent setting, we recommend this be deleted.


Response: EPA has made a policy determination that the selection of uncertainty factors is a science policy judgment. Similar to determining appropriate levels of risk, determining uncertainty factors consists of a number of competing policy considerations.

Neither ORD nor OCSPP are in a position to address this comment. At this point, you can resolve any remaining issues and continue any subsequent discussion with OMB.

With respect to the FRN, I believe David Dunlap and Lindsey Jones offered to handle development of that document. Angela and Peter should work with them on the development of the NOA.

Thanks,
Lou

Louis D'Amico, Ph.D.
Senior Science Advisor
Office of Research and Development
U.S. Environmental Protection Agency
Mail Code 8101R | 1200 Pennsylvania Ave, NW | Washington, DC 20460

Office: 202-564-4605 | Mobile:  email: damico.louis@epa.gov

From: Hoverman, Taylor <hoverman.taylor@epa.gov>

Sent: Thursday, January 14, 2021 6:15 PM

To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>

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Cc: Dunlap, David <dunlap.david@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Stedeford, Todd <Stedeford.Todd@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Wheeler, Kevin <Wheeler.Kevin@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>
Subject: RE: PFAS Tox Values: OCSPP Review

I just saw the first draft of the NOA from OCSPP – Thank you OCSPP for the quick turnaround! Now onto the remaining items –

I heard that OP was giving conflicting direction despite my coordination with OP. If that is the case, please loop me into those conversations this evening so we can immediately set up a conference call to resolve any misunderstandings. Please make me aware of any specific issues immediately.

Further, I don't need the feedback from DoD or HHS in one doc – just simply forward me what you received. That should only take a few minutes.

I'll be on standby to continue following up with you all until I hear back on these items.

Taylor Meredith
Senior Advisor to the Administrator
U.S. Environmental Protection Agency
C Ex. 6 Personal Privacy (PP)
O: 202-566-2705

From: Hoverman, Taylor
Sent: Thursday, January 14, 2021 5:54 PM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Stedeford, Todd <Stedeford.Todd@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Wheeler, Kevin <Wheeler.Kevin@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>
Subject: RE: PFAS Tox Values: OCSPP Review

All,
Sorry to be a pest, but another hour+ has passed. I may be able to streamline some of the remaining work through working directly with DoD and HHS, but I need to be looped in ASAP so I can help. As the manager of the PFAS Action Plan deliverables, I'm here to help with coordination both internally and with our other federal partners – please let me help!

Taylor Meredith
Senior Advisor to the Administrator
U.S. Environmental Protection Agency
C Ex. 6 Personal Privacy (PP)
O: 202-566-2705

From: Hoverman, Taylor
Sent: Thursday, January 14, 2021 4:33 PM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>
Cc: Dunlap, David <dunlap.david@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Stedeford, Todd <Stedeford.Todd@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Fischer, David <Fischer.David@epa.gov>;

Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Wheeler, Kevin <Wheeler.Kevin@epa.gov>; D'Amico, Louis <DAmico.Louis@epa.gov>; Jones, Lindsey <jones.lindsey@epa.gov>

Subject: Re: PFAS Tox Values: OCSPP Review

Since almost an hour has passed, I'm following up here. Please loop me in on any requested changes. If the edits aren't being made to the most recent changes in the redline, then I will have a conversation with HHS and DoD.

Taylor Meredith

Ex. 6 Personal Privacy (PP)

Sent from my iPhone. Please excuse typos or brevity.

On Jan 14, 2021, at 3:48 PM, Hoverman, Taylor <hoverman.taylor@epa.gov> wrote:

Can I please see the other agency comments and responsive changes?

Taylor Meredith

Ex. 6 Personal Privacy (PP)

Sent from my iPhone. Please excuse typos or brevity.

On Jan 14, 2021, at 3:26 PM, Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov> wrote:

Cmts are still coming in and just learned there may be others

Is it possible for Lindsey to draft the FR – but note we have several issues raised by DoD and HHS that OCSPP is addressing. It may take a while to work out w OMB

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

DC
Cell Ex. 6 Personal Privacy (PP)

From: Dunlap, David <dunlap.david@epa.gov>

Sent: Thursday, January 14, 2021 12:03 PM

To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>

Cc: Hoverman, Taylor <hoverman.taylor@epa.gov>; Dunn, Alexandra <dunn.alexandra@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>; Stedeford, Todd <Stedeford.Todd@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Wheeler, Kevin <Wheeler.Kevin@epa.gov>

Subject: Re: PFAS Tox Values: OCSPP Review

Jennifer,

What are the "other processes?"

Where does it say that this assessment must be noticed with an FRN?

Regardless, we should be able to post a pre-publication copy ASAP.

DDD

Sent from my iPhone

On Jan 14, 2021, at 10:44 AM, Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov> wrote:

Just received HHS cmts this am.

And with the new OIRA memo, we can no longer just simply post. Once we get final sign off on edits from OMB, it has to go thru other processes and noticed thru the FR before posting. Wont happen quickly from what I am being told

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

DC
Ce Ex. 6 Personal Privacy (PP)

From: Hoverman, Taylor <hoverman.taylor@epa.gov>
Sent: Thursday, January 14, 2021 10:43 AM
To: Dunn, Alexandra <dunn.alexandra@epa.gov>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Stedeford, Todd <Stedeford.Todd@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>; Wheeler, Kevin <Wheeler.Kevin@epa.gov>
Subject: Re: PFAS Tox Values: OCSPP Review

All,

Just following up here -

What's the status of the PFBS tox assessment? I heard OMB had minor comments. Can this be cleaned up and posted by tomorrow at noon?

Thanks,

Taylor Meredith

Ex. 6 Personal Privacy (PP)

Sent from my iPhone. Please excuse typos or brevity.

On Jan 8, 2021, at 4:52 PM, Hoverman, Taylor
<hoverman.taylor@epa.gov> wrote:

All,

Great news! To address the concern raised yesterday, OMB has agreed to conduct expedited review of the PFBS toxicity assessment to help make this happen! I hate to do this to you on a Friday evening, but OMB needs this to go into ROCIS today. I am attaching the redline that included OCSPP's edits. I accepted edits to spacing only and kept all other changes in redline and made 1 editorial change to incorporate OCSPP's comment. The same change was made on pages 77 and 79.

Since we have a window of opportunity to get this across the finish line, I appreciate your help doing so. Please give me a call if you need any additional help from me to get this done.

Thank you all in advance!

Taylor Meredith
Senior Advisor to the Administrator
U.S. Environmental Protection Agency
C: Ex. 6 Personal Privacy (PP)
O: 202-566-2705

From: Dunn, Alexandra <dunn.alexandra@epa.gov>
Sent: Thursday, January 7, 2021 1:44 PM
To: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov>; Hoverman, Taylor <hoverman.taylor@epa.gov>; Henry, Tala <Henry.Tala@epa.gov>; Jones, Samantha <Jones.Samantha@epa.gov>; Behl, Betsy <Behl.Betsy@epa.gov>
Cc: Stedeford, Todd <Stedeford.Todd@epa.gov>; Lowit, Anna <Lowit.Anna@epa.gov>; Fischer, David <Fischer.David@epa.gov>; Dunlap, David <dunlap.david@epa.gov>; Bertrand, Charlotte <Bertrand.Charlotte@epa.gov>
Subject: RE: PFAS Tox Values: OCSPP Review

Yes, Jennifer and I did talk and I will confer with Taylor.

Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
US Environmental Protection Agency
Washington, DC

From: Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov<<mailto:Orme-Zavaleta.Jennifer@epa.gov>>>
Sent: Thursday, January 7, 2021 1:21 PM
To: Hoverman, Taylor
<hoverman.taylor@epa.gov<<mailto:hoverman.taylor@epa.gov>>>; Dunn, Alexandra
<dunn.alexandra@epa.gov<<mailto:dunn.alexandra@epa.gov>>>; Henry, Tala
<Henry.Tala@epa.gov<<mailto:Henry.Tala@epa.gov>>>; Jones, Samantha
<Jones.Samantha@epa.gov<<mailto:Jones.Samantha@epa.gov>>>; Behl, Betsy
<Behl.Betsy@epa.gov<<mailto:Behl.Betsy@epa.gov>>>
Cc: Stedeford, Todd
<Stedeford.Todd@epa.gov<<mailto:Stedeford.Todd@epa.gov>>>; Lowit, Anna
<Lowit.Anna@epa.gov<<mailto:Lowit.Anna@epa.gov>>>; Fischer, David
<Fischer.David@epa.gov<<mailto:Fischer.David@epa.gov>>>; Dunlap, David
<dunlap.david@epa.gov<<mailto:dunlap.david@epa.gov>>>; Bertrand, Charlotte
<Bertrand.Charlotte@epa.gov<<mailto:Bertrand.Charlotte@epa.gov>>>
Subject: RE: PFAS Tox Values: OCSPP Review

Taylor, Alex and I spoke last night and you should connect with her. I was not aware of the discussion with the Administrator and I believe he did not have complete information in that discussion.

ORD will not be able to make this change and have this document go out next week. ORD's document for PFBS was considered final when the OCSPP comments were received. The type of changes OCSPP proposes would require us to go through the whole process of intra/inter-agency review and WH Technical workgroup review which will take anywhere from 6-8 months.

Happy to talk further

Jennifer Orme-Zavaleta, PhD
Principal Deputy Assistant Administrator
Office of Research and Development
US Environmental Protection Agency

From: Hoverman, Taylor
<hoverman.taylor@epa.gov<<mailto:hoverman.taylor@epa.gov>>>
Sent: Thursday, January 7, 2021 1:11 PM
To: Dunn, Alexandra
<dunn.alexandra@epa.gov<<mailto:dunn.alexandra@epa.gov>>>; Henry, Tala
<Henry.Tala@epa.gov<<mailto:Henry.Tala@epa.gov>>>; Jones, Samantha
<Jones.Samantha@epa.gov<<mailto:Jones.Samantha@epa.gov>>>; Behl, Betsy
<Behl.Betsy@epa.gov<<mailto:Behl.Betsy@epa.gov>>>
Cc: Stedeford, Todd
<Stedeford.Todd@epa.gov<<mailto:Stedeford.Todd@epa.gov>>>; Lowit, Anna
<Lowit.Anna@epa.gov<<mailto:Lowit.Anna@epa.gov>>>; Fischer, David
<Fischer.David@epa.gov<<mailto:Fischer.David@epa.gov>>>; Dunlap, David
<dunlap.david@epa.gov<<mailto:dunlap.david@epa.gov>>>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov<<mailto:Orme-Zavaleta.Jennifer@epa.gov>>>; Bertrand, Charlotte
<Bertrand.Charlotte@epa.gov<<mailto:Bertrand.Charlotte@epa.gov>>>
Subject: RE: PFAS Tox Values: OCSPP Review

Thanks for looping me in, Alex.

Yes, Tala's emails are correct. Since the Administrator has already weighed in, I assume the remaining step is to incorporate OCSPP's edits. I understand that once these changes are incorporated, the PFBS final toxicity assessment will be ready to post online.

The Administrator has a PFAS interview next Thursday. The PFAS regulatory determination should be published next week, and since this is so close to completion, I would really like us to get this tox assessment finalized before then as well, so he can highlight both actions in that interview.

This week, I have seen both a thank you note to ORD + R5 from Ohio EPA for assistance with PFAS work (Great work, ORD + R5!), as well as this InsideEPA article:
<https://insideepa.com/daily-news/new-jersey-dep-chief-mccabe-faults-epa-lack-pfas-class-policy><<https://gcc01.safelinks.protection.outlook.com/?url=https%3A%2F%2Finsideepa.com%2Fdaily-news%2Fnew-jersey-dep-chief-mccabe-faults-epa-lack->

pfas-class-
policy&data=04%7C01%7Choverman.taylor%40epa.gov
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367484867acf976aachbeca6a7%7C0%7C0%7C63745641
8606001285%7CUnknown%7CTWFpbGZsb3d8eyJWlloi
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VCI6Mn0%3D%7C1000&sdata=n1OVFenTviY4UcyTHdD
gR9d9nPdDTIKTjFJB4pV%2FQZc%3D&reserved=0>

I think next week's interview is a great opportunity for the Administrator to highlight the hard work across all EPA program offices and regions addressing PFAS and would really love if we could quickly get OCSPP's edits incorporated to add this tox assessment to the list of accomplishments.

If this is not possible, please call me today to discuss why additional time is absolutely necessary.

Thanks so much!

Taylor Meredith
Senior Advisor to the Administrator
U.S. Environmental Protection Agency
C Ex. 6 Personal Privacy (PP)
O: 202-566-2705

From: Dunn, Alexandra
<dunn.alexandra@epa.gov<mailto:dunn.alexandra@epa.gov>>
Sent: Wednesday, January 6, 2021 4:35 PM
To: Henry, Tala
<Henry.Tala@epa.gov<mailto:Henry.Tala@epa.gov>>;
Jones, Samantha
<Jones.Samantha@epa.gov<mailto:Jones.Samantha@epa.gov>>; Behl, Betsy
<Behl.Betsy@epa.gov<mailto:Behl.Betsy@epa.gov>>
Cc: Stedeford, Todd
<Stedeford.Todd@epa.gov<mailto:Stedeford.Todd@epa.gov>>; Lowit, Anna
<Lowit.Anna@epa.gov<mailto:Lowit.Anna@epa.gov>>;
Fischer, David
<Fischer.David@epa.gov<mailto:Fischer.David@epa.gov>>; Dunlap, David
<dunlap.david@epa.gov<mailto:dunlap.david@epa.gov>>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov<mailto:Orme-Zavaleta.Jennifer@epa.gov>>; Bertrand, Charlotte
<Bertrand.Charlotte@epa.gov<mailto:Bertrand.Charlotte@epa.gov>>; Hoverman, Taylor
<hoverman.taylor@epa.gov<mailto:hoverman.taylor@epa.gov>>
Subject: RE: PFAS Tox Values: OCSPP Review

+ Taylor Hoverman in the AO.

Alexandra Dapolito Dunn, Esq.
Assistant Administrator
Office of Chemical Safety and Pollution Prevention
US Environmental Protection Agency
Washington, DC

From: Henry, Tala
<Henry.Tala@epa.gov<mailto:Henry.Tala@epa.gov>>
Sent: Wednesday, January 6, 2021 1:29 PM
To: Jones, Samantha
<Jones.Samantha@epa.gov<mailto:Jones.Samantha@epa.gov>>; Behl, Betsy
<Behl.Betsy@epa.gov<mailto:Behl.Betsy@epa.gov>>
Cc: Stedeford, Todd
<Stedeford.Todd@epa.gov<mailto:Stedeford.Todd@epa.gov>>; Lowit, Anna
<Lowit.Anna@epa.gov<mailto:Lowit.Anna@epa.gov>>;
Henry, Tala
<Henry.Tala@epa.gov<mailto:Henry.Tala@epa.gov>>;
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<dunlap.david@epa.gov<mailto:dunlap.david@epa.gov>>; Orme-Zavaleta, Jennifer <Orme-Zavaleta.Jennifer@epa.gov<mailto:Orme-Zavaleta.Jennifer@epa.gov>>; Bertrand, Charlotte
<Bertrand.Charlotte@epa.gov<mailto:Bertrand.Charlotte@epa.gov>>
Subject: PFAS Tox Values: OCSPP Review
Importance: High

Sam/Betsy,

As you know OCSPP Toxicologists reviewed the PFBS and GenX draft documents; our reviews/insights are attached in format appropriate for docketing (as I understand this is something the Administrator has requested).

Also attached are the documents that include OCSPP proposed in-line edits to address the OCSPP Sr Toxicologists review, specifically relative to consideration alternative UFs, to support presentation of a range of UFs (and therefore RfDs), which I also understand the Administrator requested be included.

Please let me know if you have questions.
Tala

Tala R. Henry, Ph.D.
Deputy Director
Office of Pollution Prevention & Toxics

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E: henry.tala@epa.gov<mailto:henry.tala@epa.gov>

<PFBS clearance draft 9.30.2020_IOAA Clearance_BDR
DDD_OCSPP Edits 12-30-20.v.3 (TM).docx>